

DISCUSSION OF AMENDMENT

The specification is amended in order to replace "mutan streptococcus" with "streptococcus mutans."

Claims 1-11 are pending.

Claims 3 and 6-11 have been withdrawn from consideration.

Claims 1, 4, 5, 6, 8, and 10 are amended.

Support for the amendment to Claim 1 is found on page 54, paragraph 1.

No new matter is believed to be added upon entry of the amendment.

Upon entry of the amendment Claims 1-11 remain pending, while Claims 1-2 and 4-5 remain under consideration.

REMARKS

Applicants thank Examiner Hines for conducting the kind and courteous discussion with Applicants' representative, Daniel R. Evans, on November 9, 2005. The content of the discussion is reflected in the amendments to the claims and the following remarks.

The rejection of Claims 1-2 and 4-5 under 35 U.S.C. § 103(a) over the combination of JP 2002-357599, as evidenced by EP 1248106 (EP '106)), and S 5,817,297 (US '297) is respectfully traversed.

EP '106 does not disclose "at least one substance selected from the group consisting of sodium chloride, potassium chloride, calcium chloride, magnesium sulfate and manganese sulfate." In order to rectify this deficiency, the Office has relied on US '297. It is noted that US '297 may disclose "sodium chloride." However, the "sodium chloride" was added for the purpose of alleviation of gingival inflammation and bactericidal activity, in an amount of 3 to 35 wt % (see US '297, col. 5, lines 18-23). Moreover, US '297 is directed to a composition for enhancing oral hygiene comprising a compound selected from the group consisting of ursodesoxycholic acid and chenodesoxycholic acid. Therefore, the invention disclosed in US '297 is completely different in components, object and effects from the present invention.

On the contrary, in the present invention sodium chloride, potassium chloride, calcium chloride, magnesium sulfate or manganese sulfate is used in order to have the complex of the labeled antibody and streptococci mutans removed from the membrane retaining the labeled antibody efficiently (see line 4 from the bottom line of page 6 to line 3 of page 7 and lines 9 to 12 of page 17 etc. in the specification).

Under the above circumstances, the effect of sodium chloride is completely different between the present invention and the invention of US '297.

Applicants note that the present invention is an improvement over that which is disclosed in EP '106 by using "at least one substance selected from the group consisting of sodium chloride, potassium chloride, calcium chloride, magnesium sulfate and manganese sulfate."

The Comparative Example 1, written on pages 50 to 51 in the specification is comparable to that which is disclosed in EP '106.

In order to clarify the effect of the present invention (Example 1) compared with the invention of EP '106 (Comparative Example 1), Applicants direct the Examiner's attention to the following information. It is noted that "Method A" in this paper refers to "Example 1" in the specification and "Method B" in this paper indicates "Comparative Example 1" in the specification.

By this paper it is clear that the Example 1 using sodium chloride has high sensitivity against streptococci mutans in comparison with the Comparative Example 1 because of the existence of sodium chloride.

Table 1. Reactivity against antibody

Sample	Concentration of streptococci mutans in saliva (CFU/mL)	Method A (NaCl +)	Method B (NaCl -)
a	$1.2 \times 10^4$	-	-
b	$2.1 \times 10^5$	±	-
c	$4.5 \times 10^5$	+	±
d	$7.2 \times 10^5$	+	+
e	$9.2 \times 10^5$	++	++

Table 2. Amount of colloidal-gold labeled antibody on hold-back carrier after 15 min

Sample	Concentration of streptococci mutans in saliva (CFU/mL)	Method A (NaCl +)	Method B (NaCl -)
a	$1.2 \times 10^4$	-	+
b	$2.1 \times 10^5$	-	+
c	$4.5 \times 10^5$	-	+
d	$7.2 \times 10^5$	±	+
e	$9.2 \times 10^5$	±	+

Table 1 shows that Method A had high sensitivity against streptococci mutans than Method B.  
Table 2 shows that Method A had a better efficacy of saliva treatment than Method B.

## Method A (NaCl +)

## AD solution

1 mol/L Sodium hydroxide

1 mol/L Tris(hydroxymethyl)aminomethane

23.3% by weight of sodium chloride

## BCD solution

0.5 mol/L citric acid

1 mol/L Tris(hydroxymethyl)aminomethane

5.0% by weight of polyoxyethylen(10)octylphenyl ether

250  $\mu$ L of saliva↓ add 50  $\mu$ L of AD solution

mix

↓ add 100  $\mu$ L of BCD solution

mix

↓

Apply 100  $\mu$ L of treated saliva to the test device\*

Method B (NaCl -)

AD' solution  
1 mol/L Sodium hydroxide  
1 mol/L Tris(hydroxymethyl)aminomethane

BCD solution  
0.5 mol/L citric acid  
1 mol/L Tris(hydroxymethyl)aminomethane  
5.0% by weight of polyoxyethylen(10)octylphenyl ether

250  $\mu$ L of saliva  
↓ add 50  $\mu$ L of AD' solution  
mix  
↓ add 100  $\mu$ L of BCD solution  
mix  
↓

Apply 100  $\mu$ L of treated saliva to the test device

\*Test device: This was prepared this according to the EXAMPLE.

In view of the differences between the claimed invention and that which is disclosed in EP '106 and US '297, especially in view of the improvements made over EP '106, it is believed that the present application is in a condition for allowance. It is respectfully requested that the Examiner acknowledge the same and withdraw this rejection.

The objections to the Specification and the Claims are obviated by amendment.

The specification is amended in order to replace "mutan streptococcus" with "streptococcus mutans." Additionally, Claims 4-5 no longer are dependent on non-elected Claims 3. Claim 5 is amended for clarity.

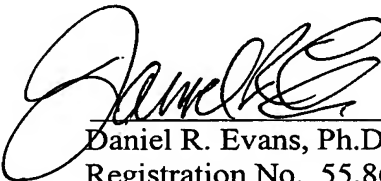
It is respectfully requested that the Examiner withdraw these objections.

The rejection of Claim 5 under 35 U.S.C. § 112, second paragraph, is obviated by the above-noted amendment of Claim 5. It is requested that the Examiner withdraw this rejection.

In view of the amendments to the claims and the remarks contained herewith, it is believed that the present application is now in a condition for allowance. Should the Examiner deem that a personal or telephonic interview would be helpful in advancing this application toward allowance, she is encouraged to contact Applicants' undersigned representative at the below-listed telephone number.

Respectfully submitted,

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